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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,117	01/08/2002	Donald F. DePalma	CRD0918	4482
27777	7590	06/10/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			MILLER, CHERYL L	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/041,117	Applicant(s) DEPALMA ET AL.	
	Examiner Cheryl Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 2, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-35-9 and 19-24 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 24 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 24 recites, "the gasket is engaged with the second prosthesis at a position along the first prosthesis *that is disposed within an aneurysm.*" Applicant is positively claiming the aneurysm, which is a portion of the body and considered non-statutory subject matter. It is suggested to include language such as *adapted to, configured to*, etc.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites the limitation "the graft material" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "the graft material" to recite, --the graft--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 6, 19-22 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Quinn (USPN 6,645,242 B1, previously cited). Referring to claim 1, Quinn discloses a system for bypassing an aneurysm comprising a first prosthesis (100), including a conduit having a proximal end (top of fig. 1, 8, 9) and a distal end (bottom of fig. 1, 8, 9), the conduit establishing a single fluid flow channel (235), the conduit comprising a stent structure (210, 215, 220) and a

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graft (200) covering the stent structure, a compressible gasket (280) positioned inside of the conduit and secured to the stent structure (215, 210, 220, stent may extend entire length of conduit, col.8, lines 38-42), and at least one second prosthesis (300) in fluid communication with the first prosthesis (100), the compressible gasket (280) including at least one aperture (270 or 250) for receiving the at least one second prosthesis (300), the compressible gasket (280) being configured to provide a seal between the first prosthesis (100) and the at least one second prosthesis (300) and to position the at least one second prosthesis within the first prosthesis such that a fluid flow path is established.

Referring to claim 6, Quinn discloses the second prosthesis (300) comprising a stent (310, 320) and a graft material (302) communicating with the stent.

Referring to claim 19, Quinn discloses a gasket (280) integrally formed with the graft (200, see figures).

Referring to claim 20, Quinn discloses a gasket (280) comprising an open cell foam material (materials listed see col.8, lines 54-61; capable of cellular invasion, col.9, lines 16-21; polyurethane, polyethylene, and PTFE which are disclosed by applicant in the specification as being open cell foam materials well known in the art, pg.21, lines 9-12).

Referring to claim 21, Quinn discloses a gasket (280) substantially impervious to fluid, creating a seal between the first and second prostheses (fluid tight seal, col.9, lines 20-22; col.5, lines 47-49).

Referring to claim 22, Quinn discloses at least one of the second prostheses (300) matingly engaged with the gasket (280) at a position *proximate* to the distal end (bottom) of the first prosthesis (near the distal end in the figures).

Referring to claim 24, Quinn discloses a first prosthesis (100) of sufficient length to extend from a healthy region of a neck into an aneurysm and a gasket (280) engaged with the second prosthesis (300) at a position along the first prosthesis (100) adapted to be disposed within an aneurysm (is capable of doing so).

Claims 1, 5, 6, 19-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Dereume et al. (USPN 6,554,858 B2, previously cited). Referring to claim 1, Dereume discloses a system for bypassing an aneurysm comprising a first prosthesis (1), including a conduit having a proximal end (top of fig. 1, 5) and a distal end (bottom of fig. 1, 5), the conduit establishing a single fluid flow channel (fig. 1 at cross section II and IV), the conduit comprising a stent structure (3) and a graft (4) covering the stent structure, a compressible gasket (5, 6) positioned inside of the conduit and secured to the stent structure (3), and at least one second prosthesis (13) in fluid communication with the first prosthesis (1), the compressible gasket (5, 6) including at least one aperture (7, 8) for receiving the at least one second prosthesis (13), the compressible gasket being configured to provide a seal between the first prosthesis and the at least one second prosthesis and to position the at least one second prosthesis within the first prosthesis such that a fluid flow path is established.

Referring to claim 5, Dereume discloses a gasket (5, 6) configured to receive two second prostheses (has two apertures, 7 and 8 for two second prostheses).

Referring to claim 6, Dereume discloses the second prosthesis (13) comprising a stent (14) and a graft material (15) communicating with the stent.

Referring to claim 19, Dereume discloses a gasket (5, 6) integrally formed with the graft (4).

Referring to claim 21, Dereume discloses a gasket (5, 6) substantially impervious to fluid, creating a seal between the first and second prostheses (col.5, lines 39-44; fig.7).

Referring to claim 22, Dereume discloses at least one of the second prostheses (13) matingly engaged with the gasket (8) at a position *proximate* to the distal end of the first prosthesis (see fig.11, 12, the gasket may extend further distally, in that case, would be engaged at the distal end; col.5, lines 63-65).

Referring to claim 23, Dereume discloses at least one second prosthesis (13) matingly engaged with the gasket (5, 6) at the distal end of the first prosthesis (the gasket may extend further distally, in that case, would be engaged at the distal end; col.5, lines 63-65).

Referring to claim 24, Dereume discloses a first prosthesis (1) of sufficient length (see figures) to extend from a healthy region of a neck into an aneurysm and a gasket (5, 6) engaged with the second prosthesis (13) at a position along the first prosthesis adapted to be disposed within an aneurysm.

Claims 1, 5, 6, 19, 21, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes (USPN 5,843,160, previously cited). Referring to claim 1, Rhodes discloses a system for bypassing an aneurysm comprising a first prosthesis (20A), including a conduit having a proximal end (top) and a distal end (bottom), the conduit establishing a single fluid flow channel, the conduit comprising a stent structure (26, 28) and a graft (22) covering the stent structure, a compressible gasket (90s; see fig.6) positioned inside of the conduit and secured to the stent

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structure (28), and at least one second prosthesis (20B, 20C) in fluid communication with the first prosthesis (20A), the compressible gasket (90s) including at least one aperture (P in fig.6) for receiving the at least one second prosthesis (20B, 20C), the compressible gasket (90s) being configured to provide a seal between the first prosthesis and the at least one second prosthesis and to position the at least one second prosthesis within the first prosthesis such that a fluid flow path is established.

Referring to claim 5, Rhodes discloses a gasket (90s) configured to receive two second prostheses (20B, 20C).

Referring to claim 6, Rhodes discloses the second prosthesis (20B, 20C) comprising a stent (34, 36, 38) and a graft material (32) communicating with the stent.

Referring to claim 19, Rhodes discloses a gasket (90s) integrally formed with the graft (22, fig.6).

Referring to claim 21, Rhodes discloses a gasket (90s) substantially impervious to fluid, creating a seal between the first (20A) and second prostheses (20B, 20C).

Referring to claim 22, Rhodes discloses at least one of the second prostheses (20B, 20C) matingly engaged with the gasket (90s) at a position *proximate* to the distal end of the first prosthesis (is near the distal end, fig.1, 2).

Referring to claim 24, Rhodes discloses a first prosthesis (20A) of sufficient length to extend from a healthy region of a neck into an aneurysm and a gasket (90s) engaged with the second prosthesis (20B, 20C) at a position along the first prosthesis (20A) adapted to be disposed within an aneurysm (see figures).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER